

**REMARKS:**

The Office Action mailed May 5, 2008, and the prior art relied upon therein has been carefully reviewed. The claims in the application remain as claims 1-10 and 34-47, and these claims define novel and unobvious subject matter, whereby these claims should be allowed. Favorable reconsideration and allowance are earnestly solicited.

Acknowledgement by the PTO of the receipt of applicant's paper is filed under §119 is noted.

Claim 4 has been rejected under the second paragraph of §112 as including the phrase "or the like" which renders such claim indefinite.

Accordingly, claim 4 has now been amended to delete "or the like" and place the claim in better form for US practice.

Applicant notes that no other rejections have been imposed under §112, and that applicant's claims have also not been objected to as a matter of form, and applicant is proceeding in reliance thereof.

Claim 1 has been amended slightly to place it in better form for U.S. practice. Thus, what was previously recited as an optional feature with respect to the surface or

surfaces of the shunt being coated with a plurality of charged species is now a required featured. In addition, the preamble of claim 1 has been amended to specify that the individual undergoing treatment in the claimed method will at some point have the toxic substance in the cerebrospinal fluid (CSF) itself. In this regard it is important to understand that the CSF itself is not the toxic substance, but the toxic substance is something (well explained in applicant's specification) which has entered the CSF from the brain where it has caused a toxic effect, also as well explained in applicant's specification.

Claims 1, 10, 34-41 and 43 have been rejected under §102 as being anticipated by applicant's earlier US patent 6,283,934 (Borgesen '934). This rejection is respectfully traversed.

In the sentence spanning pages 3 and 4 of the Office Action, in particularly in the top line on page 4, the examiner takes the position that the CSF itself in excess is a toxic substance. Applicant respectfully but strongly disagrees. The present invention deals with the removal of toxic substance present in the CSF (cf. application as filed page 13, line 15, and lines 28-30). Several examples of such toxic substances are provided in the application as filed, e.g. at page 13, line 30 to page 14, line 12. It follows from

the term "toxic" that these are substances which are substantially not present in the CSF under normal, i.e. non-pathological, physiological conditions.

The applicant agrees that excess CSF can lead to a pathological condition, namely hydrocephalus. However, it does not follow from this that the excess CSF as such is a toxic substance. This would be equivalent to claiming that the blood involved in a cerebral haemorrhage is a toxic substance. In both cases the proper interpretation is that it is not the CSF or the blood as such which is toxic, but instead its un-physiological accumulation which leads to a pathological condition. In other words, it is the accumulation of the substance, not the substance as such, which leads to the pathological condition. Indeed, removed excess CSF could in principle be returned to the person from which it was removed, e.g. to remedy an over-drainage of CSF. This clearly demonstrates that the excess CSF does not constitute a toxic substance.

The law is clear that claims are to be read in light of the supporting disclosure. Applicant's disclosure makes very clear what is meant by "toxic substances", and it is not excess CSF. Those skilled in the art, highly skilled individuals, would fully understand that excess CSF is not a

toxic substance in the context of the present application, as explained above.

Moreover, claim 1 and the claims which depend therefrom further define non-obvious subject matter in the first claimed step of "providing" the specified shunt system which includes the coating of "a plurality of charged species capable of increasing the hemocompatibility of the [hemocompatible] surface,... ." Borgesen '934 does not disclose such subject matter and does not anticipate any of applicant's claims.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1, 10, and 34-47 have been rejected under §102 as anticipated by the applicant's earlier application published as US 2002/0045847 (Borgesen '847). This rejection is respectfully traversed.

Borgesen '847, like Borgesen '934, does not show (disclose) the features noted above in conjunction with the rejection based on Borgesen '934. Accordingly, applicant respectfully repeats by reference the remarks made above against the rejection under §102 based on Borgesen '934.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 2-6 and 9 have rejected as obvious under §103 from Borgesen '934 in view of Saul et al. USP 6,383,159 (Saul). This rejection is respectfully traversed.

The Examiner proposes that one skilled in the art could have used the method of the Borgesen '934 patent to treat patients at risk of the conditions listed by Saul. However, the applicant points out that the claims of the present application are directed to: "A method for shunting toxic substances, ... wherein

- i) either all or part of the internal or external surface of the shunt body, or
  - ii) either all or part of ii) the internal or external surface of the brain ventricle catheter , or
  - iii) either all or part iii) the internal or external surface of the sinus catheter
- comprises a biocompatible/hemocompatible material comprising an inert surface preventing biological material contact with a plurality of charged species capable of increasing the hemocompatibility of the surface, ...."

The use of such a coating is disclosed by neither the Borgesen '934 Borgesen '159. The use of the coating has the effect of increasing the hemocompatibility of the coated

surface (c.f. application as filed, page 27, lines 13-20). It has surprisingly been found by the applicant that the coated shunt system used in the present invention significantly reduces some of the problems associated with the currently known shunts. Saul does not make up for the absence of such a teaching in Borgesen '934; so even if the combination were obvious, the resultant reconstructed Borgesen '934 would not reach the claimed subject matter.

Furthermore, the method disclosed by Borgesen '934 deals with shunting of excess CSF from a brain ventricle in relation to the pathological condition of hydrocephalus. In relation to its use in hydrocephalus, Borgesen '934 teaches that the preferred resistance to flow in the shunt system is 10 mmHg/ml/min and that the flow resistance should be within the range of 8-12 mmHg/ml/min (cf. col.4, lines 5-8). Such flow resistances are suitable when removing excess CSF from a brain ventricle with an above-normal pressure due to accumulation of CSF. In particular, a flow resistance within the range disclosed in the Borgesen '934 patent prevents the removal of CSF from a normotensive brain ventricle (cf. col. 5, lines 53-55). However, this also means that the shunt system disclosed in Borgesen '934 is unsuitable for removing toxic substances from a brain ventricle in which there is no excess of CSF.

The applicant therefore respectfully submits that the skilled person would not have reached a solution to the problem solved by the present invention by employing the method of the Borgesen '934 patent for the purposes disclosed in the Saul patent.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 2-6 and 9 have also been rejected as obvious under §103 from Borgesen '847 in view of Saul. This rejection is also respectfully traversed.

Borgesen '847 shows, suggests, teaches and makes obvious no more than does Borgesen '934. Therefore, the proposed combination of Borgesen '847 in view of Saul, even if such combination were obvious, would provide no more than the proposed combination of Borgesen '934 in view of Saul. Accordingly, applicant's remarks against the §103 rejection based on Borgesen '934 in view of Saul are respectfully repeated by reference.

The provision of the coating as specified in claim 1 is disclosed neither by Borgesen '847 nor Saul, so no combination of the two would reach the claimed subject matter. Moreover, the use of the coating has the effect of increasing the hemocompatibility of the coated surface (see page 26, lines 26-32, and page 27, lines 13-29 of applicant's

specification). It has surprisingly been found by the applicant that the coated shunt system provided and used in the claimed method significantly reduces some of the problems associated with currently known shunts.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 7 and 8 although indicated in the Office Action summary as being rejected, do not appear to be included in any of the rejections. Thus claims 7 and 8 have not been rejected and applicant must conclude that these claims are deemed by the PTO to define patentable subject matter. Applicant is proceeding in reliance thereof, and applicant respectfully reserves the right to redraft allowable claims 7 and 8 in independent form.

As regards the prior art documents of record which have not been applied against any of applicant's claims, applicant understands that these documents are deemed by the PTO to be insufficiently material to warrant their application against of applicant's claims, and applicant is proceeding in reliance thereof.

Applicant believes that all issues raised in the Official Action have addressed above in a manner which should

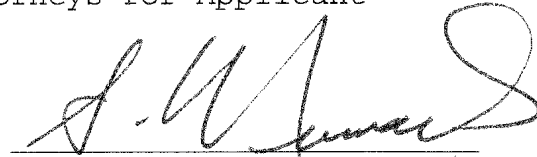


lead to patentability of the present invention. Accordingly,  
favorable reconsideration and early formal allowance are  
respectfully requested.

Respectfully submitted,

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